K070226

Summary of Safety and Effectiveness

This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR §807.92.

Submitter:

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MAR 0 9 2007

Name of the Device: CardioCT

Predicate Device: The CardioCT is substantially equivalent to the Comprehensive Cardiac Analysis (CCA) module of the "Brilliance CT, Private Practice CV configuration" CT Scanner, manufactured by Philips Medical Systems Inc.

Description of the Device: The CardioCT (CCT) is a software application for viewing, evaluating and functionally analyzing cardiac CT images. The application is an interactive tool for radiologists and cardiologists and is used to visualize coronary anatomy, assess the state of the coronary arteries and execute functional analyses of the heart. This is accomplished by segmenting the heart tissues and coronary arteries and performing detailed evaluations of the coronary arteries and ventricular functions.

Intended Use: The system that is comprised of diagnostic reading software is intended for use by radiologists as an interactive tool for analyzing radiological data and generating radiology reports based on their analysis.

Comparison of Technological Characteristics: The technological characteristics of the CardioCT are all found in the predicate device.

January 11, 20076

Date

Mr. Naor Shina, CEO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Shina Systems Ltd.
c/o Mr. Eli M. Orbach
International Regulatory Consultants
POB 6718
Efrat 90435
ISRAEL

MAR 0 9 2007

Re: K070226
Trade/Device Name: CardioCT
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 11, 2007
Received: January 24, 2007

Dear Mr. Orbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use (separate page):

510(k) Number (if known) K070226

Device Name CardioCT

Indications For Use:

The system, which is comprised of diagnostic reading software, is intended for use by cardiologists and radiologists as an interactive tool for viewing and analyzing cardiac CT data for determining the presence and extent of coronary obstructive disease.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use_____ OR Over The Counter Use_____

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off) (Optional Format 1-2-96)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K070226